UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,407	09/01/2004	Jocelyne Franchi	26274	8362

20529 7590 11/14/2008

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER	
CARTER, KENDRA D	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
11/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,407	FRANCHI ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-84* is/are pending in the application.

4a) Of the above claim(s) *36-39,45-66,70-73 and 80-83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-35,40-44,67-69,74-79 and 84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/31/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 19, 2008 has been entered.

The Examiner acknowledges the applicant's remarks and arguments of August 14, 2008 made to the office action filed September 14, 2008. Claims 31-84 are pending. Claims 31 and 67 are amended and claims 36-39, 45-66, 70-73 and 80-83 are withdrawn.

In light of the Applicant's arguments, the following rejections are withdrawn: 1) the 35 U.S.C. 103(a) rejection of claims 31-32, 34-35, 40-42 and 84 as being obvious over Bombardelli et al. in view of Jackson et al.; 2) the 35 U.S.C. 103(a) rejection of claim 33 as being obvious over Bombardelli et al. in view of Jackson et al. as applied to claims 31-32, 34-35, 40-42 and 84 above, and further in view of Streekstra et al.; and 3) the 35 U.S.C. 103(a) rejection of claims 43-44 as being obvious over Bombardelli et al.

in view of Jackson et al. as applied to claims 31-32, 34-35, 40-42 and 84 above, and further in view of Andre et al.

For the reasons in the previous office action and below, the Applicant's arguments of the following rejections were found not persuasive, and thus the rejection is upheld: 1) the 35 U.S.C. 103(a) rejection of claims 67, 69 and 74-76 as being obvious over Jackson et al., iin view of Bombardelli et al.; 2) the 35 U.S.C. 103(a) rejection of claim 68 as being obvious over Jackson et al., in view of Bombardelli et al. as applied to claims 67, 69 and 74-76 above, and further in view of Streekstra et al.; 3) the 35 U.S.C. 103(a) rejection of claim 77 as being obvious over Jackson et al., in view of Bombardelli et al. as applied to claims 67, 69 and 74-76 above, and further in view of Andre et al.; and 4) the 35 U.S.C. 103(a) rejection of claims 67, 69, 74 and 78-79 as being obvious over Jackson et al., in view of Andre et al.

Due to the Applicant's arguments were found persuasive for claims 31-35, 40-44 and 84, the new 35 USC 103(a) rejections are made below. The previous 35 USC 103(a) rejections for claims 67-69 and 74-79 are modified below due to amendments in the claims.

The Applicant's arguments are addressed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(1) Claims 67, 69 and 74-76 are rejected under 35 U.S.C. 103(a) as being obvious over Jackson et al. (U.S. Patent No. 5,578,641), in view of Bombardelli et al,. (U.S. Patent No. 5,679,358).

Jackson et al. teaches a composition for topical application to the skin comprising from 0.0001 to 10% by weight of one or more ceramide pathway intermediates (see abstract, in particular.) Jackson et al. teaches that the composition can be applied to human skin for the eradication or reversal of skin aging, removal of rough or dry skin and improving the loss of elasticity and flexibility of skin, among others (see column 2, lines 50-60, in particular.) Jackson teaches that a preferred ceramide pathway intermediate is phytosphingosine (see column 4, lines 14-20, in particular.)

Jackson et al. also does not specifically teach providing a topical composition with a lipolytic agent, as recited in claim 67. However, Jackson et al. does teach that further cosmetic adjuvants can be provided in the composition (see column 11, line 30 through column 1, line 15, in particular.)

Bombardelli et al. teaches a composition comprising esculoside in combination with an adenylate cyclase stimulator (lipolytic agent) in topical formulations (see abstract, in particular.) Bombardelli et al. teaches that the ingredient can act to improve skin early aging, particularly face and neck skin (see column 3, lines 1-12, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the ingredients including the adenylate cyclase stimulator of Bombardelli et al. in the composition of Jackson et al, because Jackson et al. teaches applying a composition to reduce wrinkles associated with skin aging, and teaches the composition can have other adjuvants, and Bombardelli et al. teaches that ingredients including an adenylate cyclase stimulator act to improve skin aging. Thus, one of ordinary skill in the art would have been motivated to provide an adjuvant comprising the adenylate cyclase stimulator-containing ingredients of Bombardelli et al. in the wrinkle-treating composition of Jackson et al, with the expectation of providing a composition that treats signs of the early aging of skin such as skin wrinkles. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third

composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.) Accordingly, claim 67 is considered to be obvious over the references.

It is respectfully pointed out that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963.) Thus the intended use recited in claim 67, namely that the cosmetic composition is "notably intended for reducing subcutaneous excess fat," and "said agents being comprised in said composition in an efficient amount for reducing subcutaneous fat" is not afforded patentable weight. The Examiner has provided a motivation to combine above, in which comprise effective amounts in the composition to treat wrinkles and cellulite.

Regarding claim 69, Jackson et al. teaches that the composition for topical application to the skin can comprise from 0.0001 to 10% by weight of one or more ceramide pathway intermediates such as phytosphingosine, as discussed above, and thus teaches an amount that meets and/or overlaps with the amount recited in the

claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of phytosphingosine provided in the composition, according to the guidance provided by Jackson et al, to provide a composition having desired properties, such as desired skin treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 74, Bombardelli et al. teaches providing an adenylate cyclase stimulator (activating agent), as discussed for claim 67 above. Regarding claim 75, Bombardelli et al. teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular.) Regarding claim 76, Bombardelli et al. teaches that the adenylate cyclase stimulator can comprise from about 0.1 to 1% of the composition (see column 1, lines 40-65, in particular), and thus teaches an amount that meets the limitations of the claims. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of adenylate cyclase stimulator provided in the composition, according to the guidance provided by Bombardelli et al. to provide a composition having desired sin treatment effects. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges

by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

(2) Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (U.S. Patent No. 5,578,641), in view of Bombardelli et al,. (U.S. Patent No. 5,679,358) as applied to claims 67, 69 and 74-76 above, and further in view of Streekstra et al. (WO 00/53568).

Jackson et al and Bombardelli et al. are applied as discussed for claims 67, 69 and 74-76 above, and teach applying a composition to skin comprising a ceramide pathway intermediate, such as phytosphingosine, to provide an antiaging effect, and also teach that the same parts of the body in need of an anti-aging effect can be those in need of a slimming effect. Jackson et al. and Bombardelli et al. also teach that the composition can comprise an adenylate cyclase inhibitor. Jackson et al. furthermore teaches that the composition can be provided with water as a vehicle (see column 6, lines 15-20, in particular.)

Jackson et al. and Bombardelli et al. do not specifically teach providing phytosphingosine in the form of phytosphingosine hydrochloride, as recited in claim 68.

Streekstra et al. teaches that forming the salt of sphingoid bases, such as the hydrochloric acid salt phytosphingosine, provides a sphingoid compound having better

solubility in topical formulations containing water than their free base counterparts (see page 2, lines 1-35, and page 3, lines 15-17, and Example 3, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the phytosphingosine hydrochloride of Streekstra et al. in the phytosphingosine-containing composition of Jackson et al, with the expectation of providing a phytosphingosine form having improved solubility in the water-containing vehicle of Jackson et al.

(3) Claim 77 is rejected under 35 U.S.C. 103(a) as being obvious over Jackson et al. (U.S. Patent No. 5,578,641), in view of Bombardelli et al,. (U.S. Patent No. 5,679,358), as applied to claims 67, 69 and 74-76 above, and further in view of Andre et al. (U.S. Patent No. 5,709,864).

Jackson et al. and Bombardelli et al. are applied as discussed for claims 67, 69 and 74-76 above, and teach a composition comprising phytosphingosine and an adenylate cyclase stimulator, and a method for applying the composition to the skin. Bombardelli et al. furthermore teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular.)

Jackson et al. and Bombardelli et al. do not specifically teach providing an adenylate cyclase stimulator that is an extract of Coleus forskohlii or Plectranthus barbatus, as recited in claim 77.

Andre et al. teaches that an extract of Coleus forskohlii contains forskoline (forskolin) and is known for its activity in stimulating adenylate cyclase (see column 5, lines 60-68, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was known would have found it obvious to provide the Coleus forskohlii extract of Andre et al. in the phytosphingosine and adenylate cyclase stimulator composition and method of Jackson et al. and Bombardelli et al, because Jackson et al. and Bombardelli et al. teach that an adenylate cyclase stimulator such as forskolin can be provided, and Andre et al. teaches that an extract of Coleus forskohlii provides the forskolin adenylate cyclase stimulator. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the extract of Andre et al. in the composition and/or method of Jackson et al. and Bombardelli et al, with the expectation of providing a suitable forskolin containing adenylate cyclase stimulator in the composition. Accordingly, claim 77 is obvious over the teachings of Jackson et al, Bombardelli et al. and Andre et al.

(4) Claims 67, 69, 74 and 78-79 are rejected under 35 U.S.C. 103(a) as being obvious over Jackson et al. (U.S. Patent No. 5,578,641), in view of Andre et al. (U.S. Patent No. 5,709,864).

Jackson et al. is applied as discussed above, and teaches a method for application to the skin of a formulation comprising phytosphingosine. Jackson et al. further teaches that the composition can be used in the treatment of skin to reduce or delay the development of wrinkles associated with advancing age or with sun-induced aging (see column 2, lines 10-20, in particular.) Jackson et al. also teaches that further cosmetic adjuncts can be provided in the composition (see column 11, line 30 through column 1, line 15, in particular.)

Jackson et al. does not specifically teach providing a composition with a lipolytic agent as recited in claims 67, 69 and 74-79.

Andre et al. teaches that an extract of Tephrosia purpurea provides powerful stimulation activity of the enzyme adenylate cyclase (lipolytic agent) (see column 1, lines 30-45, in particular.) Andre et al. teaches that the extract can be provided in a cosmetic composition to provide anti-aging effects (see abstract, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the extract of Andre et al. in the composition of

Jackson et al, because Jackson et al. teaches applying a composition to reduce wrinkles associated with skin aging, and teaches the composition can have other adjuvants, and Andre et al. teaches that an extract that acts as an adenylate cyclase has anti-aging effects in cosmetic compositions. Thus, one of ordinary skill in the art would have been motivated to provide an adjuvant comprising the extract of Andre et al. in the wrinkle-treating composition of Jackson et al. and applying to skin, with the expectation of providing a composition that treats aging of skin such as wrinkles and has anti-aging effects. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Regarding the composition of claim 67, it is noted that Jackson et al. teaches a topical composition for reducing wrinkles associated with ageing, whereas Andre et al. teaches that a composition with an extract that is an adenylate cyclase enzyme stimulator (activating agent) can provide anti-aging effects. Jackson et al. also teaches that the composition can comprise a cosmetically acceptable vehicle (see column 5, lines 60-68, in particular), as recited in the claim. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the adenylate cyclase activating extract of Andre et al. in the wrinkle-treating composition of Jackson et al., with the expectation of providing a composition

that treats aging of skin such as skin wrinkles and has anti-aging effects. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.) Accordingly, the composition of claim 67 is also obvious over Jackson et al. and Andre et al.

It is respectfully pointed out that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963.) Thus the intended use recited in claim 67, namely that the cosmetic composition is "notably intended for reducing subcutaneous excess fat," and "said agents being comprised in said composition in an efficient amount for reducing subcutaneous fat" is not afforded patentable weight. The Examiner has motivation to combine the prior art and agents above, in which effective amounts to treat wrinkles and cellulite are taught.

Regarding claim 74, Andre et al. teaches that the extract is an adenylate cyclase enzyme activator.

Regarding claim 69, Jackson et al. teaches a cosmetic composition comprising 0.1% phytosphingosine (see Example 1, in particular), and thus teaches providing the weight percentage recited in the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of phytosphingosine provided in the composition, according to the guidance provided by Jackson et al, to provide a composition having desired skin treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 78-79, Andre et al. teaches that the extract can be from Tephrosia purpurea, and also teaches that the extract can be provided in a topical composition in an amount between 0.01 to 5% by weight (see column 1, lines 45-55 and column 2, lines 20-25, in particular), which meets the range limitation recited in claim 79. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of extract provided in the composition, according to the guidance provided by Andre et al, to provide a composition having desired treatment properties. It is noted that "[W]here

the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

(5) Claims 31-32, 34-35, 40-42 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bombardelli et al (U.S. Patent No. 5,679.358), in view of Jackson et al. (U.S. Patent No. 5,578,641), in further view of Pelletier et al. (US 2002/0042438 A1).

Bombardelli et al. teaches the topical application of a composition comprising esculoside in combination with an adenylate cyclase stimulator (lipolytic agent) (see abstract, in particular.) Bombardelli et al. teaches that the composition is topically applied for treatment of cellulitis or unesthetisms connected with a deposit of superfluous fat (see abstract in particular.) Thus, it is considered that Bombardelli et al. teaches a method of application of a composition on the part or parts of the body presenting subcutaneous fat, as recited in claims 31 and 32, and also teaches the composition having a lipolytic agent that is an adenylate cyclase enzyme activating agent, as in claims 35 and 40. Bombardelli et al. also teaches that the composition can act to improve skin early aging, particularly face and neck skin (see column 3, lines 1-12, in particular.)

Bombardelli et al. does not specifically teach providing a slimming effective amount of a phytosphingosine compound, as recited in claim 31.

Pelletier et al. teaches that in the course of ageing of the skin, the physicochemical properties of the collagen change, and this collagen becomes more difficult to dissolve and to degrade. The result is a regidification of the tissues, essentially leading to a loss of tonicity of the skin. (see paragraph 8). The skin has a characteristic "orange-peel" appearance of cellulite an effect of ageing. Specifically, in cellulite, the glycation of the collagen constituting the majority of the connecting sections results in a regidification of the tissues, which then imprison the fat globules. The skin thus shows a succession of bumps formed by fatty lumps and of hollows formed by rigidified connection sections, which are characteristic of the "orange-peel" appearance (see paragraph 9). The invention treats age related loss of tonicity of the skin (i.e. cellulite) for slimming or refining the silhouette or contours of the face (see paragraph 46). Thus, Pelletier et al. teaches that by treating cellulite and other age related loss of tonicity skin problems, one can achieve a slimming effect.

Jackson et al. teaches a composition for topical application to the skin comprising from 0.0001 to 10% by weight of one or more ceramide pathway intermediates (see abstract, in particular.) Jackson et al. teaches that the composition can be applied to human skin for the eradication or reversal of skin aging, removal of rough or dry skin and improving the loss of elasticity and flexibility of skin, among others (see column 2,

lines 50-60, in particular.) Jackson teaches that a preferred ceramide pathway intermediate is phytosphingosine (see column 4, lines 14-20, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the phytosphingosine of Jackson et al. in the cellulitis and unesthetism treatment composition and method of Bombardelli et al, because Bombardelli et al. teaches treating cellulites and unesthetisms, such as those associated with skin aging, via topical application of the compositions, whereas Jackson et al. teaches that ceramide pathway intermediates such as phytosphingosine can be topically applied to reduce wrinkles associated with skin aging. Thus, one of ordinary skill in the art would have been motivated to provide the skin-aging and wrinkle treating phytosphingosine ingredient of Jackson et al, in the cellulites and skin aging unesthetism treating composition and method of Bombardelli et al, with the expectation of providing a composition and method that treats skin unesthetisms such as cellulitis and other signs of the early aging of skin such as skin wrinkles. Further, as taught by Pletier et al. by treating cellulite, one can achieve a slimming effect (see paragraph 46). Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

It is furthermore noted that the 0.0001 to 10% by weight amount of ceramide pathway intermediate taught by Jackson et al. is considered to meet and/or overlap with the "slimming effective amount" as recited in claims 31 and 34, and an amount that can stimulate the synthesis of leptin by adipocytes, as in claim 84. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of phytosphingosine provided in the composition, according to the guidance provided by Jackson et al. and Bombardelli et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Accordingly, claim 31 is considered to be obvious over the teachings of Bombardelli et al. and Jackson et al.

Regarding claim 41, Bombardelli et al. teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular.) Regarding claim 42, Bombardelli et al. teaches that the adenylate cyclase stimulator can comprise from about 0.1 to 1% of the composition (see column 1, lines 40-65, in particular), and thus teaches an amount that meets the limitations of the claims. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of adenylate cyclase stimulator provided in the composition, according to the guidance provided by Bombardelli et al. to provide a composition having desired skin treatment effects. It is

noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

(6) Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bombardelli et al (U.S. Patent No. 5,679.358), in view of Jackson et al. (U.S. Patent No. 5,578,641), in further view of Pelletier et al. (US 2002/0042438 A1), as applied to claims 31-32, 34-35, 40-42 and 84 above, and further in view of Streekstra et al (WO 00/53568).

Bombardelli et al., Jackson et al. and Pelletier et al. are applied as discussed for claims 31-32, 34-35, 40-42 and 84 above, and teach applying a composition to skin comprising a ceramide pathway intermediate, such as phytosphingosine, and an adenlyate cyclase inhibitor, to treat cellulites and other unesthetisms associated with aging, such a skin wrinkles. Pelletier et al. provides the teaching that by treating cellulite and other age related skin problems one can achieve a slimming effect (see paragraph 46). Bombardelli et al. furthermore teaches that the composition can be provided with a pharmaceutically acceptable carrier and exemplifies compositions containing water as a carrier (see column 1, lines 58-62, and Examples I-III and V, in particular.)

Bombardelli et al., Jackson et al. and Pelletier et al. do not specifically teach providing phytosphingosine in the form of phytosphingosine hydrochloride, as recited in claim 33.

Streekstra et al. teaches that forming the salt of sphingoid bases, such as the hydrochloric acid salt phytosphingosine, provides a sphingoid compound having better solubility in topical formulations containing water than their free base counterparts (see page 2, lines 1-35, and page 3, lines 15-17, and Example 3, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the phytosphingosine hydrochloride of Streekstra et al. in the phytosphingosine-containing composition of Bombardelli et al. and Jackson et al, with the expectation of providing a phytosphingosine form having improved solubility in a water-containing vehicle of Bombardelli et al., Jackson et al., and Pelletier et al.

(7) Claims 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bombardelli et al (U.S. Patent No. 5,679.358), in view of Jackson et al. (U.S. Patent No. 5,578,641), in further view of Pelletier et al. (US 2002/0042438 A1), as applied to claims 31-32, 34-35, 40-42 and 84 above, and further in view of Andre et al. (U.S. Patent No. 5,709,864).

Bombardelli et al., Jackson et al. and Pelletier et al. are applied as discussed for claims 31-32, 34-35, 40-42 and 84 above, and teach applying a composition to skin comprising a ceramide pathway intermediate, such as phytosphingosine, and an adenlyate cyclase inhibitor, to treat cellulites and other unesthetisms associated with aging, such a skin wrinkles. Pelletier et al. provides the teaching that by treating cellulite and other age related skin problems one can achieve a slimming effect (see paragraph 46). Bombardelli et al. furthermore teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular.)

Bombardelli et al., Jackson et al. and Pelletier et al. do not specifically teach providing an adenylate cyclase stimulator that is an extract of Coleus forskohlii or Plectranthus barbatus, as recited in claim 43, or that is an extract of the plant Tephrosia purpurea, as recited in claim 44.

Andre et al. teaches that an extract of Coleus forskohlii contains forskoline (forskolin) and is known for its activity in stimulating adenylate cyclase (see column 5, lines 60-68, in particular.) Andre et al. also teaches that an extract of Tephrosia purpurea provides powerful stimulation activity of the enzyme adenylate cyclase (lipolytic agent) (see column 1, lines 30-45, in particular.) Andre et al. teaches that the extracts can be provided in a cosmetic composition to provide anti-aging effects (see abstract, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was known would have found it obvious to provide the Coleus forskohlii extract or Tephrosia purpurea extracts of Andre et al. in the phytosphingosine and adenylate cyclase stimulator composition and method of Bombardelli et al. and Jackson et al, because Bombardelli et al. and Jackson et al. teach that an adenylate cyclase stimulator such as forskolin can be provided, and Andre et al. teaches that an extract of Coleus forskohlii provides the forskolin adenylate cyclase stimulator, and that Tephrosia pupurea extract also provides an adenylate cyclase activating agent. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the extracts of Andre et al. in the composition and/or method of Bombardelli et al. and Jackson et al, with the expectation of providing a suitable forskolin containing adenylate cyclase stimulator in the composition and method. Accordingly, claims 43-44 are obvious over the teachings of Bombardelli et al, Jackson et al, Pelletier et al. and Andre et al.

Response to Arguments

Applicant's arguments filed have been fully considered but they are not persuasive. The arguments of claims 31-35, 40-42 and 84 are mute in view of withdrawal of the previous rejections.

Claims 67-69 and 74-77 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,578,641 to Jackson et al., in view of Bombardelli et al. Streekstra et al, and Andre et al.

> The Applicant argues that each and every limitation of the presently claimed invention is not taught or suggested in the combination references. Jackson et al. does not teach the use of phytosphingsine as a lipolytic agent. Like Jackson et al., Bombardelli et al., Streekstra et al., or Andre et al. do not teach or suggest the use of phytosphingosine as a slimming agent. As such, the subject matter of claims does have a structural difference over the cited art despite the Examiner's assertion to the contrary. The instant claims are directed to the new and unexpected use of phytosphingosine as a slimming agent, which was in no way identified in the cited art. Therefore, it is apparent that the unexpected new use discovered by the inventors is unobvious for one skilled in the art and support patentability of the composition.

The Examiner disagrees because first, the claims are drawn to a cosmetic composition containing phytosphingosine and at least one lipolytic agent not the phytosphingosine as a lipoytic agent. Second, since the claims are drawn to a composition, the use does not get patentable weight. In regards to claims having a structural difference over the cited art, the Examiner respectfully disagrees because although Jackson et al. or Bombardelli do not individually teach the specific combination of phytosphingosine and a lipolytic agent, the combined teachings of Jackson et al., Bombardelli et al., Streekstra et al. and Andre et al. renders the composition obvious for reasons stated in the office action.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. D. C./
Examiner, Art Unit 1617

/Shengjun Wang/

Primary Examiner, Art Unit 1617